

REMARKS

Claims 1, 9, 14 and 16 were objected to in view of certain informalities. These claims 1, 9, 14 and 16 have been duly amended in accordance with the Examiner's astute and helpful comments.

In the Official Action, existing claims 1-17 were rejected as follows:

- Claims 1, 2, 5-8, 10 and 14-17 under 35 U.S.C. § 102(b) as being anticipated by Jolly et al 5,827,309.
- Remaining claims 3, 4, 9 and 11-13 under 35 U.S.C. § 103(a) as being obvious over Jolly et al '309 in view of Jolly et al 5,741,289.

~~Detailed reasons for the claim rejections were set out in the Official Action (for which the applicant is indeed appreciative).~~

Reconsideration of the applicant's claims, as set forth hereinafter, is respectfully requested.

Prior to a review of the claims, and to put this case in proper perspective, a review of the noted references — Jolly et al '309 and Jolly et al '289 — in the light of the truly applicable prior art, is in order.

The basic concept of a guarded surgical scalpel equipped with a blade stripper is clearly disclosed (and broadly claimed) in the earlier Abidin et al patents ---- 5,496,340 and 5,662,669 ---- noted in applicant's Information Disclosure Statement which, indeed, is the present applicant's *own prior art*.

Abidin et al '669 is a continuation of Abidin et al '340 filed on July 19, 1994.

Jolly et al '309 filed on October 19, 1994 is a continuation-in-part (C.I.P.) of Jolly et al 5,752,968 filed on January 27, 1995 which, in turn, is a C.I.P. of Jolly et al 5,620,454 filed on October 25, 1994. In so far as the Jolly et al patents are concerned, the first disclosure was in their '968 patent which was filed on January 27, 1995 approximately five (5) months after Abidin et al '340.

Abidin et al are the true first inventors of a combination guarded surgical scalpel and blade stripper and its basic concept.

In implementing this concept and its methodology, a preferred embodiment thereof is disclosed and claimed in Abidin et al '340 and '669 and involves the following method steps:

- Slide the guard rearwardly.
- Press a "button" (preferably in one embodiment, on the side of the handle).
- This actuates a cam (or wedge) and lifts the rearward end of the blade away from the cleat on which the blade is mounted.
- This "arms" the mechanism for subsequently stripping the blade.
- The guard is then slid forwardly to strip (or pop) the used blade off the scalpel.

The applicant's invention requires a two-hand operation, and this is an important feature of the claimed invention. [See pg. 8, lines 21...of applicant's specification.]

Now, while this mechanism is completely operative and fulfills the purposes intended, the present inventors (Dr. Abidin and Mr. Lehmbeck) realized that it may be *possible* during a surgical procedure to inadvertently press the side button inwardly on the scalpel, thereby arming the stripper;

and if the guard would be inadvertently slid forwardly, the used blade would be ejected or popped off which, conceivably, could cause serious problems in the O.R.

To alleviate this possibility, however remote, the present inventors conceived and designed a *lock-off* for the stripper; this lock-off is the subject of the present application.

In the present invention, a top button 20 is cantilevered on the handle (on which the blade is mounted) and the button is depressed downwardly to clear a transverse pin or locking stud 34 from a hook 35 thereby removing the lock-off; and, thereafter, the blade stripper 32 may be slid forwardly, such that a beveled edge 38 on the stripper 32 lifts the rearward portion 39 of the blade 23, laterally thereof, to enable the guard 14 — when slid forwardly — to strip the blade 23.

This preferred structure is a *positive manually-releasable lock* on the blade stripper 32.

Jolly 35 al '309 does *not* have a positive manually-releasable lock on the blade stripper. The blade stripper may be engaged inadvertently.

Jolly et al '309 (col. 6, lines 36-48 and Figs. 19-16) discloses a cantilevered spring arm having an integral button extending therebelow. When the button is pushed upwardly, a wedge on the forward (distal) end of the spring arm is lodged between the cleat and the rearward tang of the blade and is *maintained* in that position by means of a shoulder 91' on the spring arm. Their stripper is attached; ours is not.

This is the exact *opposite* of applicant's present invention.

The function of shoulder 91' is to maintain the spring arm in its *biased position* in which the blade stripper is armed. As recited in col. 6, lines 36-45 of Jolly et al '309:

"In another embodiment shown in Figs. 14-16, the detent mechanism merely comprises a shoulder 91' that holds the bottom of spring arm 46 in the biased position so wedge 47 is in the interface between blade cleat 49 and blade tang 57. See Fig. 14. Once guard 30 is advanced to eject blade 50 from blade carrier 40, shoulder 91' no longer engages spring arm 46 because shoulder 91' is extended past spring arm 46. This allows spring arm 46 to be returned to its unbiased (unarmed) position. "

The same is true of the previous embodiment shown in Jolly et al '309 (see Figs. 9-10) and as recited in col. 6, lines 22-35 of Jolly et al '309.

"Wedge 47 and blade carrier 40 are configured to provide a detent mechanism that holds wedge 47 in the interface between blade cleat 49 and blade tang 57. Specifically, blade cleat 49 is formed with a shoulder 90, that engages the shoulder 91 formed between wedge 47 and spring arm 46. In this way, the user need not constantly squeeze spring arm 46 to raise blade tang 57. Instead, shoulders 90 and 91 hold wedge 47 in the interface between blade cleat 49 and blade tang 57 while blade 50 remains on blade carrier 40. See Fig. 12. While blade 50 is connected to blade cleat 49, blade 50 serves to force shoulders 90 and 91 into engagement with one another. Once blade 50 has been removed from blade carrier 40, shoulders 90 and 91

disengage to allow spring arm 46 to return to its unbiased position."

(emphasis added)

The mechanism of *Jolly et al* '309 will allow for a one-handed stripping operation. Our method requires two-hands to operate and thus presents an inadvertent or accidental stripping of the blade, especially during a surgical procedure in the O.R.

Completely contrary thereto, in the applicant's present invention, the stripper mechanism is *not* armed and ready to "go" once the guard is moved forwardly. Rather, the stripper mechanism is locked off. Normally, the applicant's stripper cannot be slid forwardly at all. Again, it is normally in its locked position. The lock must be released — requiring a deliberate manual manipulation — to clear the stud on the depressible top button from the hook on the back of the stripper; and only then can the stripper be slid forwardly to lift the back edge of the blade laterally away from the cleat. The stripper is then in its "armed" position, which corresponds to the normally "biased" position of the stripper in *Jolly et al* '309, and thereafter (in both cases) the guard may move forwardly to engage the blade and eject it from the scalpel handle.

Again, in *Jolly et al* '309, there is simply *no* locking mechanism to absolutely prevent the cantilevered spring arm 46 with its integral downwardly-extending button 46a from being moved or jarred inadvertently; and once so moved or jarred, the shoulders 90, 91 (91') actually maintain the stripper mechanism "armed". The operating room surgeon or the assistants (nurses and teachers in the O.R.) may not even realize that the stripper of *Jolly et al* '309 is armed and ready to go; and if the

blade is advanced forwardly, albeit inadvertently or accidentally, the used blade will pop off and wind up ~~almost any place~~ in the sterile surgical field or almost anywhere in the O.R.

The Examiner has stated that Jolly et al '309 discloses ----

"an improvement comprising a manually-releasable lock 37 on the blade stripper to present an accidental or inadvertent stripping of the blade off the scalpel."

With all due respect, however, it appears that the Examiner has been misled or misinformed.

Element 37 of Jolly et al '309 is *not* a lock, much less a manually-releasable lock. Element 37 is a notch 37 on the sidewall 32 of guard 30. Notch 37 is complementary to notch 59 on the tang 57 (rearward portion) of blade 50. The matching (complementary) notches 37 and 59 on guard 30 and blade 50, respectively, assure a good engagement between guard 30 and blade 50 in the process of stripping the blade as the guard is slid forwardly.

As clearly stated in col. 5, lines 53-63 of Jolly et al '309:

"As shown in Figs. 6 and 7, blade carrier 40 may include a notch 45 formed therein that mates with another notch 50 formed in the blade tang 57. In addition, sidewall 32 of guard 30 can have a notch 37 that matches notch 45. This configuration may be used, if desired, to ensure that only the appropriate blades are used with guarded surgical scalpel 10. In addition, this configuration provides another benefit. By slightly lifting blade tang 57, notch 37 of guard 30 can engage notch 59. Once these notches are engaged, guard 30 can be advanced distally to force blade 50 from blade carrier 40." (emphasis added)

Clearly, notch 37 cannot be considered a lock-off at all.

Indeed, their stripper mechanism locks ON; ours locks OFF. We have a true safety feature; they do not.

Nor can the button 35 on the cantilevered top arm 34 of the guard 30 of Jolly et al '309 (see Figs. 1-2) be considered a lock-off to disable the stripper mechanism. Button 35 facilitates movement of the guard 30 in its retracted and advanced positions to expose and cover the blade 50, respectively; and by depressing the button 35, a pin 36 carried by the top cantilevered spring arm 34 clears a respective pocket 26, 26' on the sidewall 21 of the handle 20, thereby providing the detented positions of the guard and defining the extent of longitudinal movement of the guard with respect to the housing while providing an available "click" (which, again, is clearly stated in other Abidin et al patents, such as 5,275,616 per applicant's Information Disclosure Statement).

Jolly et al 5,741,289 discloses a three-piece guarded surgical scalpel including an elongated handle, a guard nested *within* the handle (not externally thereof) and connected thereto for limited longitudinal movement and notary (pivotable) movement with respect to the handle, and a separable blade carrier nested within the guard and mounted for longitudinal movement thereto and, further, having notary (pivotable) movement with respect to the handle. The blade carrier has an integrally-formed downwardly-projecting cantilevered spring arm (like the '309 patent) for initiating the blade-stripping process.

Further, in Jolly et al '289, the blade carrier 40 is locked to the handle 20 by means of a transverse pin 43 carried by the blade carrier 40 and retained within a step 28a of a cut-out 28 in the

handle 20. To unlock the blade carrier 40 from the handle 20, the proximal (rearward) portion of the blade carrier 40 is depressed to move pin 43 out of the step 28a in the cut-out 28. The blade carrier 40 may then be moved forwardly a slight distance to bring pins 41 and 42 on the blade carrier 40 into alignment with the respective vertical portions of the L-shaped slots 27 in the handle 20. As a result, the blade carrier 40 may be *rotated* up and away from handle 20 and about the axis of the pin 43 which acts as a pivot point. Thereafter, the guard 30 (being fully retracted) may be rotated (pivoted) about flanges 36 in the longitudinal slots 26 formed in the handle 20; and continued upward movement of the blade carrier 40 completely disengages the blade carrier 40 and the guard 30 away from the handle 20 ~~thereby enabling the scalpel 10 to be easily cleaned and sterilized~~. Their scalpel opens up, but does *not* come apart for effective cleaning and sterilization. [Please see col. 7, lines 24-60 of Jolly et al '289.]

Moreover, the transverse pivot pin 43 of Jolly et al '309 retains the blade carrier 40 to the handle 20 and, when enabled, provides the fulcrum for pivoting the blade carrier 40 and ultimately the guard 30 out of the handle 20.

Of significance, the pin 43 has absolutely nothing to do with locking the blade stripper and preventing an inadvertent accidental ejection of the blade and, especially, preventing longitudinal (axial) sliding movement of the blade stripper. The whole purpose of the pin 43 in Jolly et al '289 is to facilitate cleaning and sterilization, not to prevent an inadvertent or accidental actuation of the blade stripper.

Moreover, the bottom button 46a of the cantilevered spring arm 46 of Jolly et al '289 is for actuating the cantilevered spring arm 46 and the wedge 47 thereon to deflect or lift the back portion of the blade 57 away from the cleat 49 on the blade carrier 40. The button 46a has absolutely nothing to do with *disabling* the spring arm 46 and thereby *preventing* its actuation. It is simply *not* a lock-off for the stripper.

In a preferred embodiment of the applicant's present invention, as shown in EXHIBIT A attached hereto and made a part hereof, the blade stripper 32 has a side button 36 slidably guided for longitudinal movement within a slot 37 on the guard 14. The rearward portion of the blade stripper 32 has a hook 35 for receiving a locking stud 34. This locking stud 34 is carried by a depressible top button 20 on a leaf spring 19 formed on the main body portion 11 of the scalpel 10.

With the stud 34 on the top button 20 received in the hook 35 of the blade stripper 32, the blade stripper is locked and cannot be slid forwardly to deflect the blade from its cleat and facilitate stripping of the blade. This is the "lock-off" (disabled) position of the blade stripper.

When the top button 20 is depressed, the stud 34 clears the hook 35 and the stripper 32 is free to be slid forwardly (longitudinally) to deflect the rearward portion (or tang) of the blade, thus "arming" the mechanism; and thereafter, the retracted guard may be slid forwardly (longitudinally) to eject or strip the blades.

In both Jolly et al '309 and '289, there is absolutely **no "lock-off" mechanism at all** to disable the blade stripper (like a safety on a gun).

Moreover, detented locking studs received in hooks may be all over the place — maybe even as far back as the ancient Romans or even the Egyptians — but *not* for our purpose and certainly not in the manner of our preferred embodiment.

Presumably, Jolly et al are well skilled in the art; but despite the ready availability of a detented locking stud, it never occurred to them to use this readily-available technology to "lock-off" or disable the blade stripper to prevent its accidental or inadvertent actuation in the critical environment of an operating room.

This is the essence of non-obviousness and the signposts of a patentable invention.

In light of the foregoing discussions, distinguishing the applicant's present invention from the cited art, let us now review the major claim rejections in the Official Action:

Claims 1, 10 and 15

Statement.

"Jolly et al '309 discloses "a manually-releasable lock 37 on the blade stripper to prevent an accidental or inadvertent stripping of the blade off the scalpel (Figures 1-2 and 14-15; col. 6, lines 36-48)".

Comment.

Unfortunately, the Examiner is misinformed. Notch 37 is *not* a lock. Notch 37 is formed on the sidewall 32 of guard 30. Notch 37 matches with notch 45 on blade carrier 40. This ensures that only the appropriate (proprietary) blades are used with the guarded surgical scalpel. [In contrast,

our invention may be used, universally, with all manufacturer's blades.]

Additionally, when the blade tang 57, ~~is lifted~~, the notch 37 on guard 30 can engage a notch 59 on the blade — the notches 37 and 59 are complementary — and the guard 30 may be advanced forwardly to stop strip (eject) the blade. [Col. 5, lines 53-64 of Jolly et al '309.]

Nor is the shoulder 91' a lock-off for the stripper. **It's exactly opposite.** The shoulder 91' holds the spring arm 46 (the stripper) in its biased or armed position with the wedge 47 in the interface between the blade cleat 49 and the blade tang 57. [Col. 6, lines 36-47 of Jolly et al '309.]

The cited prior art, in effect, "arms" the stripper for subsequent stripping (ejection) of the blade by the forwardly-advancing guard. And in a one-hand operation. As a result, the used blade could be ejected, inadvertently, during a surgical procedure. This is hardly a safety feature. Our mechanism is truly a lock-off and a definite safety feature, requiring a two-hand operation to strip the blade and thus prevent an inadvertent or accidental stripping of a used blade during a surgical procedure in the O.R.

Claims 2 and 16-17

Comment:

Element 46 is not a locking stud, nor is it carried by the depressible top button 35 on the guard 30. Element 46 is actually the cantilevered spring arm formed on the blade carrier 40. The distal

one of the cantilevered spring arm 46 has a wedge-shaped portion 47 that aligns with the interface between the blade cleat 49 and the blade 50. [See col. 6, lines 1-9 of Jolly et al '309.] Moreover, and as aforesaid, the shoulder 91' is not a hook and, besides, it maintains the blade stripper in its biased ("armed") position such that if the guard is moved forwardly from its retracted position, albeit inadvertently, the blade will be ejected.

Claim 1, as amended, calls for the forward movement of the blade stripper to be "longitudinally of the scalpel" to deflect the blade tang and enable the guard when moved forwardly, to strip the blade; while Jolly et al '309 has a cantilevered spring arm which pivots about an axis. More significantly, in the cited '309 reference, there is no — repeat no —

"manually-releasable lock on the blade stripper to prevent an accidental or
inadvertent stripping of the blade off the scalpel"

---- as recited in claim 1.

Additionally, claim 1 has been further amended to recite ---

"thereby requiring a two-hand operation and preventing an accidental or
inadvertent stripping of the blade during a surgical procedure".

Accordingly, it is respectfully submitted (and for the reasons aforesaid) that claim 1 is not anticipated, disclosed, taught, suggested or rendered obvious by the cited art ('309 and '289) and a favorable consideration of amended claim 1 and an allowance thereof is respectfully solicited.

Claims 2-8 are each dependent, directly or indirectly, on amended claim 1 and recite additional

patentable subject matter which, in combination with claim 1, heretofore were not available in the cited prior art nor in current medical practice or instruments therefor.

Additionally, claim 3 has been amended to specifically recite (*inter alia*) ----

"and wherein the blade stripper is movable independently of the guard".

Accordingly, an allowance of dependent claims 2-8 is also in order, and the same is respectfully urged.

Claim 9 is a detailed structural claim and, like claim 1, has also been amended to recite (*inter alia*) ----

"and wherein the blade stripper is movable independently of the guard".

Accordingly, an allowance of claim 9, as amended herein, is respectfully solicited.

Claim 10 has been amended to recite a blade stripper ----

"requiring a two-hand operation".

The cited prior art fails to disclose a *true* blade stripper lock at all, much less one requiring a two-hand operation.

Accordingly, an allowance of amended claim 10 is respectfully urged.

Claims 11-13 are dependent, directly or indirectly, on amended claim 10 and call for additional structure which, in combination, are not disclosed, suggested, taught nor rendered obvious by the prior art.

Accordingly, an allowance of dependent claims 11-13 is also in order, and the same is respectfully urged.

Claims 14 and 15 have been withdrawn (without prejudice or disclaimer) to narrow the issues in this case.

Claim 16, a method claim, has been carefully amended herein to recite (*inter alia*) ----

"a blade stripper movable independently of the guard",

"a lock-off on the blade stripper", (and)

"requiring a two-hand operation",

"thereby precluding an inadvertent or accidental movement of the blade stripper during use or handling of the guarded surgical scalpel".

For the reasons aforesaid, amended claim 16 is clearly *not* disclosed, suggested, taught nor rendered obvious by the prior art; and thus an allowance of amended claim 16 is respectfully urged.

Claim 17, dependent on claim 16, recites additional structure; and hence is also allowable.

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Inventors: Abidin et al

It appears that all matters have been addressed satisfactorily, and that the case is now in condition for a complete allowance; and the same is respectfully urged.

However, if the Examiner has any comments or questions, or has any suggestions as per MPEP 707.07(d) and (j), for passing the case in condition for final allowance, he/she is respectfully urged to contact the undersigned attorney-of-record at the telephone number below, so that an expeditious resolution may be effected and the case passed to issue promptly.

Respectfully submitted,

7-20-07
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